Remarks

Responsive to the Office Action dated September 29, 2005, Applicants request consideration of the following remarks. A reconsideration of the present application respectfully is requested. Claims 10-11 and 17-20 have been canceled. Claims 21 and 22 have been added. As such, claims 1-9, 12-16 and 21-22 are pending and under consideration. Each of these claims are believed to be in condition for allowance and such favorable action is requested. Applicants would like to thank the Examiner for her time in interviewing the case on December 19, 2005.

103 Rejections

35 U.S.C. § 103(a) Rejections

To establish a *prima facie* case of obviousness, three criteria must be met:

1) there must be some suggestion or motivation to modify the reference or to combine reference teachings;

2) there must be a reasonable expectation of success; and

3) the prior-art references must teach or suggest all the claim limitations.

Moreover, the teaching or suggestion, and the reasonable expectation of success must be found in the prior art and not be based on Applicants' disclosure. *See* MPEP § 706.02(j), § 2142, and § 2143.

Claims 1-5 have been rejected under 35 U.S.C. 103(a) as being unpatentable over by Sugi et al. (The American Journal of Gastroenterology, Vol. 91, No. 5, 927-934, 1996) (the "Sugi reference"). As the Sugi reference neither teaches nor suggests a method for diagnosing irritable bowel syndrome if a sample does not contain an elevated level of endogenous lactoferrin, Applicants traverse the rejection.

Claim 1 recites a method for diagnosing irritable bowel syndrome and other noninflammatory etiologies by determining that a fecal sample does not contain an elevated level of endogenous lactoferrin. The Sugi reference does not teach or suggest diagnosing irritable bowel syndrome by determining a fecal sample does not contain an elevated level of endogenous lactoferrin. The Sugi reference merely teaches using fecal lactoferrin as a marker for disease activity in inflammatory bowel disease.

The Office Action of September 29, 2005 states that the "maker for inflammatory diseases would obviously preclude the detection of non-inflammatory events." This is not the case. **Lactoferrin is detectable in subjects with IBD, healthy persons as well as subjects with irritable bowel syndrome.** Thus, in order to diagnosis IBS, it would be necessary to determine the level of fecal lactoferrin in subjects with IBS (a non-inflammatory etiology). The level of fecal lactoferrin in subjects with IBS is not determined in the Sugi reference. Furthermore, it has been stated in a previous office action that the cited references are silent as to the measurement of lactoferrin in non-inflammatory disorders (See Office Action dated 3/9/05, page 6). A person of skill in the art could not develop a qualitative assay for diagnosing irritable bowel syndrome without determining the level of fecal lactoferrin in subjects with IBS. This level is needed to define a level of fecal lactoferrin to target a cut-off of the development of a diagnostic assay.

As there is no motivation or suggestion for determining the level of lactoferrin in subjects with IBS, it is not possible for the Sugi reference to teach or suggest a level of fecal lactoferrin to determine the level of fecal lactoferrin needed to diagnosis IBS. As the Sugi reference neither teaches nor suggests a method for substantially diagnosing irritable bowel syndrome by determining a fecal sample does not contain an elevated level of endogenous lactoferrin, Applicants request withdrawal of the 103(a) rejection of claim 1. As claims 2-5

depend directly or indirectly from claim 1, Applicants request withdrawal of the rejection of these claims as well.

Claims 6-9 and 12-16 have been rejected under 35 U.S.C. 103 (a) as being unpatentable over Sugi in view of Peen et al., Gut, 1993, 34, 56-62 (the "Peen reference). With respect to claims 6-9, as stated above, the Sugi reference does not teach or suggest diagnosing irritable bowel syndrome by determining a fecal sample does not contain an elevated level of endogenous lactoferrin as claimed by independent claim 1.

With reference to claims 12-16, independent amended claim 12 is drawn to an assay determining whether an enzyme-linked antibody bound sample contains an elevated level of lactoferrin as compared to a reference value for health control subjects, wherein the optical density of the enzyme-linked antibody bound sample is read at 450 nm, wherein if said enzyme-linked antibody bound sample does not contain an elevated level of endogenous lactoferrin, irritable bowel syndrome is diagnosed. As neither the Sugi reference nor the Peen reference teach nor suggest a diagnostic assay for diagnosing irritable bowel syndrome if a sample does not contain an elevated level of lactoferrin.

The Sugi reference does not teach or suggest a diagnostic assay for diagnosing irritable bowel syndrome if a sample does not contain an elevated level of lactoferrin. The level of fecal lactoferrin in subjects with IBS is not determined in the Sugi reference. Furthermore, it has been stated in a previous Office Action that the cited references are silent as to the measurement of lactoferrin in non-inflammatory disorders (See Office Action dated 3/9/05, page 6). A person of skill in the art could not develop a qualitative assay for diagnosing irritable bowel syndrome without determining the level of fecal lactoferrin in subjects with IBS. This level is needed to define a level of fecal lactoferrin to target a cut-off of the development of a diagnostic assay.

The Peen reference also does not teach or suggest a diagnostic assay for diagnosing irritable bowel syndrome if a sample does not contain an elevated level of lactoferrin. The Peen reference merely teaches detecting high frequencies of IgG anti-lactoferrin antibodies, not lactoferrin itself, in serum samples from patients with ulcerative colitis and primary sclerosing chloangitis. The Peen reference differs from independent claim 12 in that it detects IgG anti-lactoferrin antibodies in serum, not lactoferrin in fecal samples. The Peen reference also does not teach diagnosing IBS if a fecal sample does not contain an elevated level of lactoferrin as claimed by claim 12 of the present application.

As the Sugi reference and the Peen reference neither teach nor suggest a diagnostic assay for diagnosing IBS if a fecal sample does not contain an elevated level of lactoferrin, Applicants request withdrawal of the 103(a) rejection of claim 12. As claims 13-16 depend directly or indirectly from claim 12, Applicants request withdrawal of the 103(a) rejection as to these claims as well.

The present application is believed to be in condition for allowance, and Applicants request that a timely notice of allowance be issued for this case. Should any unresolved issues remain in the case, please feel free to contact the undersigned at the phone number listed below.

Respectfully submitted.

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